

510K SUMMARY OF SAFETY AND EFFECTIVENESS

The Signal Medical Corporation HHS Acetabular Component is manufactured of ASTM F-136 or F-75. The design is made available in twelve (12) sizes ranging from 48mm to 70mm, in two mm increments. The cup is coated with an F-67 sintered beaded surface for F-136 or F-75 beads for an F-75 cup to enhance bone ingrowth. The device is designed in three models, one with three circumferentially spaced pins or spikes at 120 degree intervals to provide for a primary skeletal fixation and reduce the chance of rotation, one with screw holes and one with both screw holes and spikes. The ultra high molecular weight polyethylene inserts, ASTM F648, are secured to the acetabular shell using a crown-taper fit. They are designed to accept 28mm femoral heads on their inside diameter from 48mm to 70mm and 32mm femoral heads from 54mm to 70mm. This device is intended for single use only.

Indications for use

1. Osteoarthritis
2. Rheumatoid Arthritis
3. Traumatic Arthritis
4. Where the use of a more conservative procedure has failed or is unacceptable.
5. Intended for non-cemented use, single use only

Contact Information

If further information is required, please contact Dr. Louis Serafin, Signal Medical Corporation, 3777 Lapeer Road Suite 3C, Port Huron, Michigan 48060, phone (810) 966-3917.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 04 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Louis A. Serafin, Jr., M.D.
President
Signal Medical Corporation
3777 Lapeer Road 3-C
Port Huron, Michigan 48060

Re: K022382

Trade/Device Name: HHS Acetabular Component
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated
uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: July 15, 2002
Received: July 22, 2002

Dear Dr. Serafin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

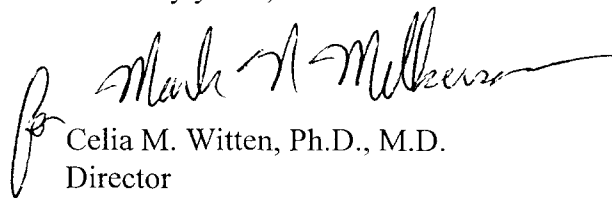
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Dr. Louis A. Serafin, Jr.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K022382

Device Name: HHS ACETABULAR HIP COMPONENT

Indications For Use:

OSTEOARTHRITIS

RHEUMATOID ARTHRITIS

TRAUMATIC ARTHRITIS

WHERE THE USE OF A MORE CONSERVATIVE
PROCEDURE HAS FAILED OR IS UNACCEPTABLE

INTENDED FOR NON-CEMENTED USE
SINGLE USE ONLY

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE
ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDREH, Office of Device Evaluation
(ODE)**

for Mark N. Milken
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022382

Prescription Use _____
Counter Use _____
(Per 21 CFR 801.105)

OR Over-The-

(Optional Format)